

PART III: CONSUMER INFORMATION

Pr Combivent® Respimat®
Ipratropium Bromide (as Monohydrate)/Salbutamol
(as Salbutamol Sulfate) Inhalation Solution

Read this carefully before you start taking COMBIVENT RESPIMAT and each time you get a refill. This leaflet is a summary and will not tell you everything about COMBIVENT RESPIMAT. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about COMBIVENT RESPIMAT.

ABOUT THIS MEDICATION

What the medication is used for:

COMBIVENT RESPIMAT is used to treat the wheezing or shortness of breath caused by COPD (chronic obstructive pulmonary disease which includes chronic bronchitis and emphysema).

What it does:

COMBIVENT RESPIMAT is a combination of two drugs that are bronchodilators: ipratropium bromide (an anticholinergic) and salbutamol (a beta-agonist). COMBIVENT RESPIMAT works by relaxing the muscle surrounding the bronchi (airways in the lungs) and therefore helps to ease breathing problems.

You may already be familiar with one or both of these bronchodilators, since they are also available separately, with a prescription as ipratropium bromide and salbutamol.

When it should not be used:

Do not take COMBIVENT RESPIMAT if:

- you are allergic to ipratropium bromide or other drugs which are anticholinergic (contain atropine or its derivatives), salbutamol sulfate, or to any component of COMBIVENT RESPIMAT (see “**What the non-medicinal ingredients are**”);
- you have a fast or irregular heart beat or have a thickened heart muscle due to various conditions;
- you are under 18 years of age.

What the medicinal ingredients are:

Ipratropium bromide monohydrate and salbutamol sulfate.

What the non-medicinal ingredients are:

Benzalkonium chloride, edetate disodium, hydrochloric acid and purified water.

What dosage forms it comes in:

Inhalation Solution.

Each puff delivers 20 mcg ipratropium bromide (monohydrate) and 100 mcg salbutamol (as salbutamol sulfate) from the mouthpiece.

The inhaler enables you to inhale the medicine contained in a cartridge. The cartridge contains 120 puffs or 60 puffs (equal to 120 doses of medicine or 60 doses of medicine) available after preparing the inhaler for first use. There is enough medicine for 30 days or 15 days when it is used as 1 puff four times a day.

WARNINGS AND PRECAUTIONS

The solution is intended for inhalation only.

Avoid getting the spray into your eyes. This may result in eye pain and/or discomfort, temporary blurring of vision, and/or coloured images in association with red eyes. Should any of these symptoms develop, consult a doctor immediately.

BEFORE you use COMBIVENT RESPIMAT talk to your doctor or pharmacist if you:

- are pregnant or intend to become pregnant;
- are breast feeding;
- are having treatment for a thyroid or adrenal gland condition;
- are having treatment for high blood pressure, angina or a heart problem;
- have diabetes;
- have low levels of potassium in your blood (hypokalemia), especially if you are taking:
 - drugs known as xanthine derivatives (such as theophylline);
 - steroids to treat asthma;
 - water pills (diuretics);
- have eye problems, such as glaucoma, or eye pain;
- are taking any other medications including eye drops or any medications you can buy without a prescription;
- have difficulty in urination;
- have enlarged prostate;
- have any allergies or reactions to foods or drugs;
- have a history of convulsions (uncontrolled shaking or seizures);
- have liver or kidney disease.

Contact your doctor immediately if:

- you require more than 1 daily dose (4 puffs); the maximum daily dose is 6 puffs;
- your shortness of breath becomes worse;
- you don't get the same benefit from your medicine as you did before;
- you have breathing difficulties and chest pain;
- you experience difficulty with urination.

COMBIVENT RESPIMAT may cause dizziness, difficulty in focusing the eye, dilated pupils, and blurred vision. You should not drive or operate machinery if this occurs.

The use of COMBIVENT RESPIMAT may test positive for performance enhancement (doping) in athletic competition.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with COMBIVENT RESPIMAT:

- digitalis;
- other anticholinergic drugs, such as ipratropium bromide and other beta₂-adrenergic agents such as salbutamol, the individual ingredients of COMBIVENT RESPIMAT;
- beta blockers, such as propranolol;
- xanthine derivatives such as theophylline;
- monoamine oxidase inhibitors such as isocarboxazid;
- tricyclic antidepressants such as amitriptyline;
- epinephrine;
- certain diuretics or “water pills” such as furosemide, hydrochlorothiazide.

PROPER USE OF THIS MEDICATION

COMBIVENT RESPIMAT has been prescribed to treat your current condition. DO NOT give it to other people. Always use COMBIVENT RESPIMAT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Appropriate use of COMBIVENT RESPIMAT includes an understanding of the way it should be administered. Therefore, it is important that you read and understand how to use the inhaler before starting COMBIVENT RESPIMAT therapy.

Dosage should be individualized.

Not recommended for use in children and adolescents under 18 years of age.

FOR ORAL INHALATION ONLY

Take care to avoid spraying COMBIVENT RESPIMAT into your eyes.

Usual Adult Dose:

1 puff four times a day.

Patients may take additional inhalations as required; however, the total number of inhalations should not exceed six in 24 hours.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If a dose is missed and no symptoms occur, the regular next dose according to the dosing schedule should be taken. If a dose is missed and respiratory symptoms are experienced, the missing dose should be taken and the dosing schedule according to the recommended dosage should be resumed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- wheezing after inhalation;
- headache, dizziness;
- nausea (feeling sick), digestive problems like constipation, diarrhoea and vomiting;
- muscle problems such as cramps, weakness, pain, feeling weak, tremor (shaking);
- feeling nervous;
- mental disorder;
- impaired voice sounds;
- increased sweating;
- bronchitis and upper respiratory tract infection (a cold);
- throat irritation, cough, dry mouth or throat, bad taste - sucking on a sour candy or rinsing your mouth may help.

Check with your doctor if the dry mouth or bad taste persists or if you experience constipation for a prolonged period of time.

COMBIVENT RESPIMAT contains a beta-agonist, and taking additional doses in the form of other single agent, beta-agonists (fenoterol, salbutamol, etc.) could cause harmful effects on the heart, lungs and circulatory system. Therefore do not take additional bronchodilators by inhalation with COMBIVENT RESPIMAT unless instructed to do so by your doctor or pharmacist.

Stop taking the medication and tell your doctor immediately if you notice any of the following:

- you are wheezy or have any other difficulties in breathing;
- you are having an allergic reaction – the signs may include skin rash, itching and nettle rash. In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and reduction of your blood pressure.

COMBIVENT RESPIMAT can cause abnormal blood test results for hypokalemia and/or ketoacidosis. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Uncommon	Bronchospasm: Increased wheezing or tightness in the chest, difficulty in breathing, coughing bouts		✓
	Shortness of breath		✓
	Hypotension or hypertension, changes in blood pressure: dizziness, fainting, lightheadedness		✓
	Skin rash		✓
Rare	Allergic reaction: rash, hives, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, choking due to swelling of the muscles around the voice box		✓
	Fast or irregular heart beat / chest pain		✓
	Eye disorders: new or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos or rainbows around items or red eyes		✓
	Urinary Retention: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓
	Muscle pain, weakness or spasms; paralysis		✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Myocardial ischaemia: decreased blood flow to the heart leading to angina (chest pain), shortness of breath, or a heart attack			✓
Angina: Chest pain			✓
Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell			✓

This is not a complete list of side effects. For any unexpected effects while taking COMBIVENT RESPIMAT, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (25°C), excursions permitted to 15-30°C. Do not freeze.

Store out of the sight and reach of children.

COMBIVENT RESPIMAT should be discarded whenever one of the following occurs first:

- at the latest, three months after you first use it (even if not all medication has been used);
- when the locking mechanism is enacted.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingenelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103 Ext. 84633.

Please visit our website to see if more up-to-date information has been posted.

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INSTRUCTIONS FOR USE

1
PUFF
FOUR
TIMES A
DAY

Introduction

Read these **Instructions for Use** before you start using COMBIVENT RESPIMAT.

You will need to use this inhaler **FOUR TIMES A DAY**. Each time you use it take 1 PUFF.

Each box contains :

- 1 RESPIMAT inhaler
- 1 cartridge

Each cartridge provides 120 puffs (120 doses). Physician samples provide 60 puffs (60 doses).

The colour of the cap of the RESPIMAT inhaler is colour coded to match the cartridge.



How to store my COMBIVENT RESPIMAT inhaler

Store COMBIVENT RESPIMAT (the cartridge and inhaler) between 15-30°C. Do not freeze.

Keep out of the sight and reach of children.

Do not use your inhaler after the expiry date.

Do not touch the piercing element inside the clear base.

If you have not used your inhaler in more than:

- 3 days: release 1 puff towards the ground
- 21 days: repeat steps 4 to 6 under “Prepare for first Use” until a cloud is visible. Then repeat steps 4 to 6 three more times.

How to care for your COMBIVENT RESPIMAT

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only. You should do this at least once a week. Any minor changes in the colour of the mouthpiece will not affect how your COMBIVENT RESPIMAT works.

When to get a new COMBIVENT RESPIMAT



- Your COMBIVENT RESPIMAT inhaler contains either 120 puffs (120 doses) or 60 puffs (60 doses) if you use it as directed (1 puff / four times a day). The 60 puffs (60 doses) product is for physician samples.
- The dose indicator shows you about how much medication is left.
- When the dose indicator **enters** the red area of the scale, there is about:
 - 7 days of medication left for the 120 puff product
 - 3 days of medication left for the 60 puff product.You need to get a new prescription or refill your prescription.
- Once the dose indicator reaches the **end** of the red scale:
 - Your COMBIVENT RESPIMAT locks automatically. No more doses can be released. At this point, the clear base cannot be turned any further.
- You should throw out the COMBIVENT RESPIMAT when one of the following happens first:
 - 3 months after first use, even if all the medication has not been used, or
 - it locks automatically.

Prepare for First Use

1

Remove clear base

- Keep the cap closed.
- Press the safety catch while firmly pulling off the clear base with your other hand.



2

Insert cartridge

- Insert the **narrow** end of the cartridge into the inhaler.
- Place the inhaler on a firm surface and push down firmly until it snaps into place.
- You should hear a “click” when it has gone in all the way.

3

Replace clear base

- Put the clear base back into place until it “clicks”.
- Do not remove the clear base again.



4

Turn

- Keep the cap closed.
- Turn the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



5

Open

- Open the cap until it snaps fully open.



6

Press

- Point the inhaler toward the ground.
- Press the dose-release button.
- Close the cap.
- Repeat steps 4 to 6 **until** a cloud is visible.
- **After a cloud is visible**, repeat steps 4 to 6 three more times.



Your inhaler is now ready to use.

Daily Use

TURN

- Keep the cap closed.
- **TURN** the clear base in the direction of the arrows on the label until it “clicks” (half a turn).



OPEN

- **OPEN** the cap until it snaps fully open.



PRESS

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents.
- While taking a slow, deep breath through your mouth, **PRESS** the dose-release button and continue to breathe in.
- Hold your breath for 10 seconds or for as long as you feel comfortable.

Close the cap.



Answers to Common Questions

It is difficult to insert the cartridge deep enough:

The dose indicator on the COMBIVENT RESPIMAT reaches zero too soon:

Did you accidentally turn the clear base before inserting the cartridge? Open the cap, press the dose-release button, then insert the cartridge.

Did you use COMBIVENT RESPIMAT as indicated (1 puff/four times a day)? COMBIVENT RESPIMAT will last 30 days if used at 1puff four times a day. Physician samples will last 15 days if used at 1 puff four times a day.

Did you insert the cartridge with the wide end first? Insert the cartridge with the narrow end first.

Did you turn the clear base before you inserted the cartridge? The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

Did you spray in the air often to check whether the COMBIVENT RESPIMAT is working? Once you have prepared COMBIVENT RESPIMAT, no test-spraying is required if used daily.

Did you insert the cartridge into a used COMBIVENT RESPIMAT? Always insert a new cartridge into a **NEW** COMBIVENT RESPIMAT.

I cannot press the dose-release button:

My COMBIVENT RESPIMAT doesn't spray:

Did you turn the clear base? If not, turn the clear base in a continuous movement until it clicks (half a turn).

Did you insert a cartridge? If not, insert a cartridge.

Is the dose indicator on the COMBIVENT RESPIMAT pointing to zero? The COMBIVENT RESPIMAT inhaler is locked after 120 puffs (120 doses). Physician samples will be locked after 60 puffs (60 doses). Prepare and use your new COMBIVENT RESPIMAT inhaler.

Did you repeat Turn, Open, Press (TOP) less than three times after inserting the cartridge? Repeat Turn, Open, Press (TOP) three times after inserting the cartridge as shown in steps 4 to 6 under "Prepare for first Use".

Is the dose indicator on the COMBIVENT RESPIMAT pointing to 0? If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your COMBIVENT RESPIMAT is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a **NEW** COMBIVENT RESPIMAT.

I cannot turn the clear base:

My COMBIVENT RESPIMAT sprays automatically:

Did you turn the clear base already? If the clear base has already been turned, follow steps "OPEN" and "PRESS" under the directions for "Daily Use" to get your dose.

Was the cap open when you turned the clear base? Close the cap, then turn the clear base.

Is the dose indicator on the COMBIVENT RESPIMAT pointing to zero? The COMBIVENT RESPIMAT inhaler is locked after 120 puffs (120 doses). Physician samples will be locked after 60 puffs (60 doses). Prepare and use your new COMBIVENT RESPIMAT inhaler.

Did you press the dose-release button when turning the clear base? Close the cap so the dose-release button is covered, then turn the clear base.

Did you stop when turning the clear base before it clicked? Turn the clear base in a continuous movement until it clicks (half a turn).